# SYSTEM TO FORM, FILL AND SEAL FLEXIBLE BAGS

## RELATED APPLICATIONS

This Application is a continuation of co-pending U.S. Application, Serial No. 09/316,165 filed May 21, 1999, which is a continuation of International Application No. PCT/IB 97/01458, filed November 18, 1997, which claims priority from Italian Patent Application No. MI 96A002451 filed on November 22, 1996, now issued as Italian Patent No. IT 1285990 B1. International Application No. PCT/IB 97/01458 and Italian Patent No. IT 1285990 B1 are hereby incorporated by reference, and made a part hereof.

## TECHNICAL FIELD

The present invention concerns a system to form, fill and seal (F.F.S.) containers of flexible plastic materials, in particular sterilizable bags containing solutions for the administration of infusion solutions. The system generally includes the phases of (1) feeding from at least one reel a plastic and flexible material in the form of a film or pellicle, preferably multilayer, forming the bag; (2) printing the material pulled from the reel; (3) winding the printed material; (4) washing the printed material; (5) aligning and folding the printed and washed film; (6) welding the folded film in a first direction; (7) feeding and applying valves on the surface of the folded and welded film; (8) making a second welding in a second direction; and, (9) cooling and cutting the bags to send to them for overwrapping and sterilizing.

## BACKGROUND OF THE INVENTION

Numerous systems exist for manufacturing flexible containers and filling them with liquids. However, only commonly assigned U.S. Patent No. 4,456,813 (corresponding to European Patent No. 142,758) describes a first efficient system that is substantially automatic for the industrial production of bags with valves and comprising the phases described herein. For quite some time this system has permitted the achievement of large industrial targets. Nevertheless, with all its merits, it has shown some limits. For example, present day demands and the requirements of

the health authorities call for several further means, such as the application of a means for bag suspension and the use of technologically advanced and complex valves. These and other valves can have zones difficult to access, i.e., cavities that would require extremely long sterilization times for safe sterilization, as compared with the time required to sterilize only the container. For example, sterilization of the container can be accomplished in about 10 minutes in an autoclave at 120 ° C, however, sterilization of the valve requires much longer times that are not industrially acceptable. In fact, water could reach the cavities either through permeability of the bag wall on which the valve is welded, or through the external surfaces of the valve itself. If the volume of the cavity is small, the danger is small, but if the volume of a bag is large, the danger is prohibitive. In addition to the increased sterilization times, there would always be uncertainty about the effectiveness of the treatment. Furthermore, in the conventional system several difficulties were incurred in sanitizing the various mechanisms, one example being that of dosing. To dose, the quantity of solution necessary to fill the bag required additional time that was not only excessive, but lacked precision. Accordingly, a system which minimizes or eliminates these drawbacks is preferred.

## SUMMARY OF THE INVENTION

The first aim of the present invention is to provide a very advanced system that does not have the disadvantages of previous systems and is characterized by high efficiency, reliability, hygiene security and maximum precision. Another aim of the invention is to provide the previous system with more efficient, less expensive and more compact treatment means. These and other aims are obtained in he system with the present invention.

## BRIEF SUMMARY OF THE DRAWINGS

The different aspects and advantages of the invention will be seen better in the following description of the forms of realization (illustrative and not limiting) shown in the accompanying figures, where:

FIG. 1 is a block diagram of the system of the present invention;

FIG. 2 is a planar representation of a first kinematics scheme of the realization of the process of FIG. 1;

FIG. 2A is the enlarged representation of a variant of a portion of FIG. 2;

FIGS. 2B and 2C are two views in partial and schematic perspective of a dry cleaning means of the present invention;

FIG. 3 is a schematic and partial perspective view illustrating one arrangement of the stages and means for the realization of the process in FIG. 1;

FIGS. 4 and 5 are two frontal views, partially in section, of two valves of the present invention;

FIGS. 6 and 7 are schematic top views of bags with the valves of FIGS. 4 and 5 and with a ring in the suspension hole of the present invention;

FIG. 8 is a partially cross-sectioned view of a means of humidifying the valves of the bags of the present invention;

FIG. 9 is the scheme of a high precision liquid dosing means of the present invention;

FIG. 10 is a lateral schematic view of the filling portion of the actuating machine, incorporating the dosing means of FIG. 9;

FIG. 11 is a lateral view of an arrangement of the print station of the present invention;

FIG. 12 is an perspective view of the valve welding station 5b;

FIG. 13 is an perspective view of the final welding and molding block of the present invention.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to FIGS. 1 and 2 the system according to the invention is substantially representable with at least 5 stations, each involving one or more treatments.

In particular, block 1 shows the stage, respectively the supplying station for the feeding of the film F from a reel B; the dashed rectangles show the possibility of placing in station 1 at least a second reel B' in parallel to the first reel B and of the same width as that, or else a reel B" of a width n times the width of B or B'.

Associated with the unwinding reel RS is a means for tension adjustment bearing a braking means DF.

According to another aspect of the invention block 2 shows a station of total printing TP on line (2a) followed by the accumulation (2b) of the thus completely printed film on line. The TP station now includes a hot printer that uses a hot press a the impression means and that lays on the bag, from a pigmented film, the characters placed on a cliché. The station TP is preset to obtain the printing of the prescription, the lot number and the data of the daily production. Furthermore through the print menu it is possible to set up the bag format (from 50 cc t 5,000 cc), the temperature and speed and all the numerous parameters needed for the printing of the bag itself.

Block 3 shows the washing station phase that consists of a single dry washing stage. There is no contact with liquids and supports. One of the preferred washing means is represented in FIGS. 2B and 2C. It is formed by two superimposed chambers 101 and 102 with a central slot for the printed film FST that is suspended and subjected to filtered air AF flowing in from three nozzles 103, 104 and 105. The air then flows out through nozzles 106, 107 and 108 after it has flowed over, and hence washed, particles and impurities from the printed film FS as shown in FIG. 2C. In the case of using more reels B, B' etc. of equal length, or a reel B" of a width n times greater than the previous ones, the stations 2 and 3 are able to operate contemporaneously on a plurality of films.

Block 4 shows the treatment of the printed film on line and dry washed, FTSL, in four subphases including: accumulation (4b) of FSTL, gimballing alignment (4d), folding (4e), and towing (4f).

In the system according to the present invention, there has been the advantageous elimination of not only the drying phase (4a) (due to dry washing) but also the phase(4c) of sterilization with ultraviolet rays UVA as described in US Patent N° 4,456,813. As can now be seen, station four is extremely more compact, efficient and reliable. The few means for performing these operations are thus the rollers (4b), (4d), (4e, 4e' with the folding prism PR) and (4f). The old squeezing rollers (4a) and the UV plate (4c) associated with the rollers having been eliminated.

The functioning of the alignment rollers (4b), the folding prism PR inserted between the rollers (4e) and (4e') and, lastly, the towing roller (4f) cooperating with

the second folding roller (4e') is now faster and safer (also because there are no stops and interruptions in the new, only four-phase, station 4).

Station 5 can now be considered "revolutionized" compared with that of our previous US patent N° 4,656,813. In fact, in station 5, bag formation by vertical and horizontal welding and application of. valve(s) and suspension rings, there are now found only substations of longitudinal (vertical) welding (5a) and valve application (5b).

FIGS. 4 and 5 show two valve structures of the types EMO-LUER and TWIN VALVE. They consist of a cap T, a valve core CV, a rubber plug GP and two cavities CA1 and CA2. In the "TWIN" valve TO indicates the part to be removed at the moment of using the product, guaranteeing the sterility of the product contained within, ZF indicates the twist-off fracture zone. The EMO-LUER valve of FIG. 5 consists of the valve core EPO-L, the rubber plug GP, the cap TT, the perforator P and the warranty seal SG that will be broken at the moment of use; OR indicates the sealing gasket. These valves are in themselves already known from the disclosure of Applicant's US Patent N° 4,467,003. Shown in FIG. 6 is a bag SA with a TWIN-VALVE valve TV at a transverse extremity, and a suspension hole in the opposite wall. Shown in FIG. 7 is a bag SA with an EMO-LUER valve (VEM) on the longitudinal side and with a suspension ring AS on the other longitudinal side.

Station 5 now also comprises: (x) a vibrator (5b1) for feeding the valves and, according to the most notable aspect of the invention; (y) a spray wetting-means (5b2) for valve cavities; (z) a means (5b3) for the detection and control of the wetting; (j) a means (5c) for making a bag suspension hole; and, (w) a means (5f) for the application of a suspension ring (in addition to, or as an alternative to, the said hole), including also a vibrator (5f1) for the supplying of the said ring.

According to an aspect of the invention the valve welder is an ultrasound one with open ring control of position and approach speed. For such a purpose, the original welding system disclosed in US Patent N° 4,656,813 has been greatly improved by the introduction of a continuous checking of the position and speed of the welding head (5b) ("sonotrode") during its approach to the anvil (represented by dashes). FIG. 12 shows the relative block (5b) comprising a position transducer (81), a cylinder (82), a slide (83), the sonotrode (84), and a transducer (85). With an

algorithm of the PID type sampled to a thousandth of a second, an optimization was carried out of the speed and the acceleration (deceleration) of the sonotrode/anvil impact, the aim being to make the whole welding operation as soft as possible (and hence reliable).

In a further aspect of the invention, the dosing of the filling liquid RIEM is done with very great precision due to a station SP, substantially automatic, comprising at least electropneumatic valves (60) and (62) fed by (61) and a processing switchboard (63). The dosing valve has a double electropneumatic thrust and permits a operating (opening/closing) of the dosage means in a time of 3 to 5 thousandths of a second, allowing a precision of +/-1 cc per dosage quantity.

In the preferred embodiment, the means is controlled by the number of impulses coming from a lobed flowmeter with Halls effect. FIG. 10 shows the arrival point AIC of the tubular feeding connection from the solution (not represented), the dosing valves of FIG. 9, the broadened extremity EA of the supply tube TE within a bag SA in the filling phase, followed by the next bag SAC (also not yet sealed at the top, till to be filled).

Still another characteristic of the invention lies in the shaping of the bags (contemporaneously with horizontal welding), through the regulation and control of the temperature of two mobile bars (71), (73) (FIG. 13) that are heated by highly efficient electric heating elements, and able to compress, weld and thermoform the bags, eliminating any possible ears. Besides the hot vulcanized bar (71), the means of FIG. 13 includes a cold bar contrasting the cutting edge (72), the second hot forward bar (73), a cutting edge support (74) and a cold support bar of the cutting edge (75).

Again use is made of a PID (Proportional, Integral Derivative) type algorithm, dynamically modified to optimize temperature control, for example on twelve interlaced points. The cooling of the welding follows immediately through the action of cooled bars (e.g. of the type 72, 75 of FIG.13) that, besides cooling and blocking the welding folding process, cuts the bags themselves to measure.

As a notable aspect of the invention, the humidification of the cavities CA1 CA2 of either the EMO-LUER or TWIN VALVE of FIGS. 4 and 5 can be carried out in various ways, for example with the means of FIG. 8, comprising a valve V1, a fluxstate FLU, a nebulization nozzle US, a piston PA to move the US served by a

sensor SEP, a bridging circuit for the observation of the electric conductability in the already wet cavity for the controlling of the correct humidification, and a discharge channel for the wetting liquid CSLB.

Even though the invention has been described with reference to the embodiment forms represented in the accompanying drawings it is obvious that it is not limited to these embodiments but is susceptible to all the variants, modifications, substitutions and such like that, being within the reach of the person skilled in the art, fall naturally within the spirit and scope of the following claims. In fact the describe means of dry washing, total printing, humidification etc. can be substituted by equivalent commercial means. Furthermore, the system according to the invention foresees the possibility not only of welding one or more valves onto the same bag but also of working on two series of bags (odds and evens) and of applying a type of valve, a ring or a suspension hole on the odd and even bags alternatively. The film and pellicle F (FIG. 1) forming the bags (SA with valves and suspension means) are preferably multilayer, consisting of (co) polymers of laminated olefins, amides, esters etc. (US patent N° 4,326,574), but better still coextruded, particularly those according to the Applicant's demands for European patent N°0658421 and International patent WO 95/16565.

Indeed, optimal results have been obtained with coextruded film based on two external layers (homogeneous chemically) of ethylene copolymers (PE) - propylene (PP) that themselves differ only in the PE content, or of two chemically diverse layers e.g., polyethylene/polypropylene. The adhesion of the two layers is ensured by an appropriate coextruded binding, also polyolefinic. By cautiously choosing the composition of the external layers, the binding and hence the adhesion between the said layers, and any possible temperature difference between the welding bars etc. bags can be obtained with optimal values of welding resistance, resistance to shocks particularly including dropping, transparency, sterilizability, etc. The coextruded films can have additional layers, these also being coextruded or even laminated onto three-layer film (two external layers and that of the binding).